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January 29, 2019

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

Test Substance:

8EHQ-18-21621

Generic Name: Haloalkane

This letter is to inform you of the results of an *in vitro* dermal corrosivity study with the above-referenced test substance. This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, because it is information in which EPA may have an interest.

The EpiDerm™ Model (EPI-200) (MatTek Corporation, MA, USA) was used to assess the potential dermal corrosivity of the test substance. The MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide) conversion assay, which measures the NAD(P)H-dependent microsomal enzyme reduction of MTT (and to a lesser extent, the succinate dehydrogenase reduction of MTT) to a blue formazan precipitate, was used to assess cellular metabolism after exposure to a test substance. The protocol was based upon the OECD guideline, "*In Vitro* Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method" (TG 431). The experimental design of this study consisted of the determination of the direct MTT reduction potential, assessment of colorant potential, a pH determination of the neat liquid test substance and/or dosing dilution, if possible, and a definitive Skin Corrosion Test. The method utilizes a 3-minute exposure for a corrosive classification and a 60-minute confirmatory exposure for materials found to be noncorrosive at the 3-minute exposure. Test materials which reduce tissue viability to <50% within 3 minutes are considered corrosive by this method. In addition, test materials which result in tissue viability of ≥50% after a 3-minute exposure, but result in tissue viability of <15% after a 60-minute exposure are also classified corrosive. Test materials which result in tissue viabilities of ≥50% after a 3-minute exposure and ≥15% after a 60-minute exposure are classified non-corrosive. Furthermore, sub-classification of corrosive materials is possible using the 3-minute exposure time as follows: a sub-category classification of 1A is assigned if the viability is <25%, and 1B/1C if the viability is ≥ 25%.

The test article was not observed to reduce MTT directly in the absence of viable cells. However, a dark gray precipitate was observed after incubation of the test article in MTT solution. At the discretion of the Study Director, a killed control experiment was performed concurrently in the screening assay to determine the extent of interference with the MTT reduction test (if any) by the test article precipitate alone. The test article was not considered to have probable photometric MTT interference. The test and control articles were tested by treating four EpiDerm™ tissues per material. Two tissues were used to assess viability after the 3-minute exposure, and two were used to assess viability after the 60-minute exposure. In addition, two killed control tissues per exposure time were treated with the test article, positive control, and negative control to correct for possible photometric interference caused by precipitate formation of the test article. Note: Possible partial tissues loss was observed via visual inspection during the MTT extraction step for viable tissue 1 and killed control tissue 2 dosed with the positive control. The mean relative viability of the test substance exposed tissues after 3 and 60 minutes of exposure was 76.8 % and 7.0 %, respectively. The pH of the test substance was 5.0. The mean relative viability of the positive control exposed tissues after 3 and 60 minutes of exposure was 20.3 % and 4.7 %, respectively. Under the conditions of this *in vitro* study, the test substance is predicted to be corrosive to skin and classified as a category 1B/1C skin irritant according to GHS.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Substantiation of our claim of confidentiality is included herewith as **Attachment 1**. Please contact me if you have any questions about this submission or need further clarification.

Sincerely,

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Attachment 1

Entire Substantiation Claimed as Confidential Business Information